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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/403,092	10/15/1999	JOACHIM HOFMANN	038311/0103	6828

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EXAMINER
ZEMAN, ROBERT A

ART UNIT	PAPER NUMBER
1645	35

DATE MAILED: 09/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/403,092	HOFMANN ET AL.	
	Examin r	Art Unit	
	Robert A. Zeman	1645	

-- The MAILING DATE of this communication appears on the cover she t with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 July 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *35-41 and 45-59* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *35-41 and 45-59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The amendment and response filed on 7-8-2003 are acknowledged. Claims 35, 37, 41 and 46 have been amended. Claims 51-59 have been added. Claims 35-41 and 45-59 are pending and currently under examination.

Objections Withdrawn

The objection to claims 24 and 30 for containing misspelled words is withdrawn. Cancellation of said claims has rendered the objection moot.

The objection to claim 24 for reciting two steps denoted as "b)" and no step denoted as "a)" is withdrawn. Cancellation of said claim has rendered the objection moot.

Objections Maintained

The objection to the specification for containing trademarks and/or tradenames is maintained for reasons of record. Applicant asserts that a skilled artisan would understand said trademarks within the context of the specification and hence they are in compliance with MPEP 608.01(v). Applicant further requests that the Examiner identify Trademarks that fail to comply with MPEP 608.01(v) by page and line. Applicant is reminded that to be in full compliance with MPEP 608.01(V), generic terminology is required to ensure that the skilled artisan would understand what said material was over the entire length of an issued patent. Moreover, it is the responsibility of the Applicant, not the Patent Office, to ensure that the specification is in compliance. Moreover, any response or amendment to this Office action that does not correct the deficiencies of the specification outlined above will not be considered fully responsive.

Claim Rejections Withdrawn

The rejection of claims 24-25 under 35 U.S. C. 112, first paragraph, based on the specification, while being enabling for oligonucleotides which comprise SEQ ID NO:8; SEQ ID NO:9; SEQ ID NO: 10; SEQ ID NO: 11; SEQ ID NO: 12; SEQ ID NO: 13; or SEQ ID NO: 14, does not reasonably provide enablement for "a part thereof" of the aforementioned oligonucleotides is withdrawn. Cancellation of said claims has rendered the rejection moot.

Claim Rejections Maintained

35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 41 is rejected under 35 U.S.C. 112, first paragraph, based on the specification, while being enabling for an isolated nucleic acid which comprises SEQ ID NO:29, does not reasonably provide enablement for "a nucleic acid that hybridizes, under stringent conditions of 6X SSC at 68°C, to a nucleotide sequence according SEQ ID NO:29" is maintained for reasons set forth in the previous Office action in the rejection of claim 23.

Applicant argues:

1. The specification defines stringent conditions in the specification.

2. The defined hybridization conditions require that the fragments be of considerable length and homology to hybridize to the described sequences.

3. A skilled artisan would not interpret the limitations as meaning "a nucleic acid consisting of as few as two nucleotides.

4. The USPTO itself considers nucleotide sequences of less than 10 nucleotides unfit for stable binding to a probe.

Applicant's arguments have been fully considered and deemed non-persuasive. As outlined in the previous Office action, the rejected claim, as written, reads on **any** nucleic acid that hybridizes to a nucleic acid with the sequence of SEQ ID NO:29. As outlined previously Lathe (Journal of Molecular Biology, 1985, Vol. 183, No. 1, pp. 1-12) teaches a minimum probe length of **16-18** nucleotides for mammalian cDNA, and a probe length of **18-20** nucleotides for mammalian genomic DNA. These numbers are based on the estimated numbers of unique sequences in a cDNA library (-107) versus a genomic library (-109). Use of smaller oligonucleotides will result in non-specific hybridization, because the smaller oligonucleotide complementary sequence will no longer be unique. One of skill in the art would not know how to use oligonucleotides of less that 16 or 18 base pairs in length in carrying out hybridization assay. **Additionally**, said claim would read on **all nucleic acids larger** in size than a nucleic acid with the sequence of SEQ ID NO:29, that would hybridize to a nucleic acid with a sequence of SEQ ID NO:29, including genomic DNA. Since the specification only describes the use of nucleic acids with the sequence of SEQ ID NO:29 and the specification provides no guidance for making said nucleic acid in accordance with the claimed invention, said specification is only enabling for the nucleic acids with the sequence of SEQ ID NO:29.

Additionally, there is no basis for Applicant's broad assertion that the recited stringent conditions place any type of **requirement** on the sequence and homology of sequences to the described sequences.

Finally, contrary to Applicant's assertion, a skilled artisan would interpret the metes and bounds of the claimed to be as little as two nucleotides and include **all nucleic acids larger** in size than a nucleic acid with the sequence of SEQ ID NO:29.

35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless —
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or m public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim

that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 35-38, 45-47, 51 and 54-56 are rejected under 35 U.S. C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over de Leeuw et al. (Veterinary Parisitology Vol. 39 No. 1-2, 1991, pages 137-147, IDS-10) for reasons set forth in the previous Office action in the rejection of claims 17-20, 29-31.

Applicant argues:

The Declaration by Mr. Cornelissen demonstrates that the claimed protein is different from that in the cited reference (de Leeuw et al.) since the protein in the cited reference and a 18kD protein disclosed by Schneider react to the same antibody and the protein disclosed by Schneider has no relation to the protein of the instant invention since the sequences are different.

Applicant's arguments have been fully considered and are deemed to be non-persuasive. The Declaration by Mr. Cornelissen has been fully considered but is not found sufficient for the following reasons:

1. The sequence of the Schneider protein, upon which Applicant relies, has not been presented or made of record and hence cannot be evaluated.

2. There is no evidence, other than a third person personal communication, to support the assertion that the Dv 3-14 protein disclosed by Schneider et al and the 17 kDa protein disclosed by de Leeuw et al. react with the same monoclonal antibody.

3. There is no direct evidence that the claimed protein would not react with the same monoclonal antibody.

4. The experiment set forth in the Declaration by Mr. Cornelissen, did not directly compare the 17kD protein of de Leeuw et al. with the claimed protein. The experiment compared crude extracts, GST fusion proteins and Dv 3-14. The conclusion reached by Mr. Cornelissen was based on indirect not direct evidence. Consequently, in the absence of direct evidence to the contrary, the rejection over de Leeuw et al. is maintained.

Claims 35-41 and 42-59 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Schnieder (International Journal of Parasitology, Vol. 22 No. 7, 1992, pages 933-938, IDS-10) is maintained for reasons set forth in the previous Office action in the rejection of 17-26 and 29-34.

Applicant argues:

1. Schneider et al. discloses an amino acid sequence of the Dv3-14 protein that is available from the NCBI protein database as entry AAB27962.

2. Said protein has only a 17% homology with SEQ ID 30 of the present Application.

Applicant's arguments have been fully considered and are deemed to be non-persuasive. The Declaration by Mr. Cornelissen has been fully considered and has been found non-persuasive since it fails to provide for the Examiner's evaluation any factual evidence to support the assertions made in said declaration (see above). Consequently, in the absence **of factual evidence** to the contrary, the protein disclosed by Schneider is deemed to be the same as that of the instant invention. The rejection over Schneider is maintained since **the sequence data** upon which Applicant relies has not been made of record and hence cannot be evaluated.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (703) 308-7991. The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Robert A. Zeman
September 15, 2003